



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ian W. Hunter and Robert Dyer  
Application No.: 10/657,734 Group Art Unit: 3763  
Filed: September 8, 2003 Examiner: Not assigned  
Confirmation No.: 8918  
Title: NEEDLELESS DRUG INJECTION DEVICE

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
<u>2/26/04</u> Date	<u>Margaret A. Norcutt</u> Signature
<u>Margaret A. Norcutt</u> Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references are enclosed.
    - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☒ The "concise explanation" requirement (non-English references) for references AP, AL2 and AM2 under 37 CFR 1.98(a)(3) is satisfied by:
  - ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☒ the enclosed English language abstracts.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [     ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[     ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

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Concord, MA 01742-9123

Dated: 2/26/4

PTO-449 REPRODUCED		ATTORNEY DOCKET NO. 0050.2048-005		APPLICATION NO. 10/657,734	
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> February 25, 2004 (Use several sheets if necessary)		FIRST NAMED INVENTOR Ian W. Hunter		FILING DATE 09/08/03	
		EXAMINER Not assigned		CONFIRMATION NO. 8918	
				GROUP 3763	

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	3,057,349	10/09/1962	Ismach
	AB	3,815,594	06/11/1974	Doherty
	AC	3,977,402	08/31/1976	Pike
	AD	4,108,177	08/22/1978	Pistor
	AE	4,206,769	06/10/1980	Dikstein
	AF	4,436,173	03/06/1984	Siposs et al.
	AG	4,744,841	05/17/1988	Thomas
	AH	4,886,499	12/12/1989	Cirelli et al.
	AI	5,116,313	05/26/1992	McGregor
	AJ	5,405,614	04/11/1995	D'Angelo et al.
	AK	5,480,381	01/02/1996	Weston
	AA2	5,505,697	04/09/1996	McKinnon, Jr. et al.
	AB2	5,622,482	04/22/1997	Lee
	AC2	5,694,920	12/09/1997	Abrams et al.
	AD2	5,722,953	03/03/1998	Schiff et al.
	AE2	5,840,062	11/24/1998	Gumaste et al.
	AF2	5,919,167	07/06/1999	Mulhauser et al.
	AG2	6,004,287	12/21/1999	Loomis et al.
	AH2	6,037,682	03/14/2000	Shoop et al.
	AI2	6,074,360	06/13/2000	Haar et al.
	AJ2	6,203,521 B1	03/20/2001	Menne et al.
	AK2	6,258,062 B1	07/10/2001	Thielen et al.
	AA3	6,272,857 B1	08/14/2001	Varma
	AB3			
	AC3			

EXAMINER	DATE CONSIDERED
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<b>PTO-449 REPRODUCED</b>  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  February 25, 2004  (Use several sheets if necessary)	<b>ATTORNEY DOCKET NO.</b> 0050.2048-005		<b>APPLICATION NO.</b> 10/657,734	
	<b>FIRST NAMED INVENTOR</b> Ian W. Hunter		<b>FILING DATE</b> 09/08/03	
	<b>EXAMINER</b> Not assigned		<b>CONFIRMATION NO.</b> 8918	<b>GROUP</b> 3763

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	EP 1 020 200 A2	07/19/2000	Weston Medical Limited		
	AM	EP 0 599 940 B1	12/29/1997	Weston Medical Limited		
	AN	EP 0 710 130 B1	12/06/2000	Weston Medical Limited		
	AO	EP 0 834 330 A2	04/08/1998	Weston Medical Limited		
	AP	WO 00/23132	04/27/2000	KSW Systemtechnik GMBH		X
	AQ	GB 686,343	01/21/1953	Becton Dickenson and Company		
	AL2	01046344 JP	02/20/2000	KAO Corp.; Nippon System		X
	AM2	06327639 JP	11/20/1994	Copal Co., Ltd.		X
	AN2					
	AO2					
	AP2					
	AQ2					
	AL3					
	AM3					
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	AL4					
	AM4					
	AN4					
	AO4					
	AP4					
	AQ4					

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  February 25, 2004  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 0050.2048-005		APPLICATION NO. 10/657,734	
	FIRST NAMED INVENTOR Ian W. Hunter		FILING DATE 09/08/03	
	EXAMINER Not assigned		CONFIRMATION NO. 8918	GROUP 3763

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR		Bischoff, J.E., <i>et al.</i> , "Finite element modeling of human skin using an isotropic, nonlinear elastic constitutive model," <i>Journal of Biomechanics</i> 33:645-652 (2000).
AS		Diridollou, S., "Sex- and site-dependent variations in the thickness and mechanical properties of human skin <i>in vivo</i> ," <i>International Journal of Cosmetic Science</i> 22:421-435 (2000).
AT		Flynn, D.M., <i>et al.</i> , "A Finite Element Based Method to Determine the Properties of Planar Soft Tissue," <i>Journal of Biomechanical Engineering</i> 120(2):202-210 (1998).
AU		He, M.M., <i>et al.</i> , "Two-Exponential Rheological Models of the Mechanical Properties of the Stratum Corneum," <i>Pharmaceutical Research</i> 13:S1-S604 (1996).
AV		Hirota, F.G., <i>et al.</i> , "An Implicit Finite Element Method for Elastic Solids in Contact," <i>IEEE</i> :136-146 (2001).
AW		Korenberg, M.J. and Hunter, I.W., "The Identification of Nonlinear Biological Systems: Volterra Kernel Approaches," <i>Annals of Biomedical Engineering</i> , 24:250-268 (1996).
AX		Lindahl, O.A., <i>et al.</i> , "A tactile sensor for detection of physical properties of human skin <i>in vivo</i> ," <i>Journal of Medical Engineering &amp; Technology</i> , 22(4):147-153 (1998).
AY		Manschot, J.F.M. and Brakkee, A.J.M., "The Measurement and Modelling of the Mechanical Properties of Human Skin <i>In Vivo</i> -I. The Measurement," <i>J. Biochem.</i> 19(7):511-515 (1986).
AZ		Manschot, J.F.M. and Brakkee, A.J.M., "The Measurement and Modelling of the Mechanical Properties of Human Skin <i>In Vivo</i> -II. The Model," <i>J. Biomechanics</i> 19(7):517-521 (1986).
AR2		Menciassi, A., <i>et al.</i> , "An Instrumented Probe for Mechanical Characterization of Soft Tissues," <i>Biomedical Microdevices</i> 3(2):149-156 (2001).
AS2		Oka, H. and Irie, T., "Mechanical impedance of layered tissue," <i>Medical Progress through Technology, Supplement to Volume 21</i> :1-4 (1997).
AT2		Patton, R.L., "Mechanical Compliance Transfer Function Analysis for Early Detection of Pressure Ulcers." Unpublished master's thesis, Massachusetts Institute of Technology, Cambridge, MA. (1999).

EXAMINER	DATE CONSIDERED
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February 25, 2004

(Use several sheets if necessary)

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DATE CONSIDERED